

## **REMARKS**

Claims 1-23 are pending. Claims 6 and 8-9 are withdrawn. Claims 1, 20, 21, 22 and 23 have been amended. The step of “treating said patient with electromagnetic radiation” has been removed from claim 1 and placed in claims 21-23. Additional amendments to claim 1 are discussed below. Claims 10, 11, 23 and 24 have been canceled. Claims 25-30 are new. Support for the new claims can be found on page 49, lines 1-10. No new matter has been added.

Importantly, the amendments and claim cancelations made herein should not be construed to be an acquiescence to any of the claim rejections. Rather, these actions are being made solely to expedite the prosecution of the above-identified application. The Applicants expressly reserve the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application (35 USC § 120).

## **INFORMATION DISCLOSURE STATEMENT**

As noted in the previous Response, the Applicants appreciate the Examiner reviewing the references cited on Information Disclosure Statement submitted on October 12, 2004. The Applicants note that the Examiner has indicated that reference CF (the International Search Report for PCT/US03/000564) was not considered because it has “not published”. However, the Applicants believe the International Search Report did publish on the WIPO website on November 6, 2003. The Applicants respectfully request that the Examiner consider the cited International Search Report.

## **RESPONSE TO CLAIM REJECTIONS UNDER 35 USC § 112¶2**

Claims 1-5, 6, 10-18 and 20-22 are rejected for failing to comply with the written description requirement; the Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, has possession of the claimed invention. Specifically, the Examiner rejects to the following claim language: “wherein the antineoplastic agent is released from the biocompatible polymer at a constant rate.”

Solely to expedite prosecution, the cited claim language has been removed from claim 1 and replaced with the claim language from claims 10 and 11. In light of this amendment, claims 10 and 11 have been canceled.

Accordingly, the Applicants respectfully request withdrawal of the 35 USC § 112¶2 based rejection of claims 1-5, 6, 12-18 and 20-22.

### **RESPONSE TO CLAIM REJECTIONS UNDER 35 USC § 103(a)**

Claims 1-5, 7, 10-18 and 20-23 have been rejected as being unpatentable over US Patent No. 5,651,986 ('986) in view of US Patent No. 6,166,173 ('173). The Examiner cites the '986 patent for disclosing a method of treating brain cancer (a central nervous system neoplasm) of a patient comprising instilling into an anatomic area of a patient affected by brain cancer a therapeutically effective amount of a composition comprising a biocompatible polymer and an antineoplastic agent. However, as noted by the Examiner, the '986 patent fails to disclose the polymer of Formula VI recited in claim 7. The Examiner asserts that the deficiencies of the '986 patent are cured by the '173 patent. Specifically, the Examiner asserts that the '173 patent has all of the structural limitations of the presently claimed biocompatible polymer/antineoplastic agent. The Applicants respectfully traverse.

Assuming *arguendo* that the Examiner has made a *prima facie* showing of obviousness, the Applicants respectfully assert that the superior properties of the claimed compositions negates such a showing because an "assumed similarity must give way to evidence that [such an] assumption is erroneous." *In re Papesch*, 315 F.2d 381, 391 (CCPA 1979). The Applicants direct the Examiner's attention to page 94, lines 18-23, of the instant application wherein the PCPP-SA implants of the '986 patent are discussed. As noted therein, the implants of the '986 patent release their antineoplastic agents in a biphasic pattern with an initial burst of drug followed by a much slower release of drug over months. Importantly, the initial burst of drug resulted in sporadic toxicity among the animals with the implants and therefore is suboptimal for clinical application. Therefore, the Applicants respectfully assert that one of skill the art would have expected to see a similar burst of drug release with the currently claimed compositions. However, as noted on page 94, lines 24-27, the use of the claimed polymeric composition unexpectedly resulted in an in vitro constant rate of release for the entire period of drug release.

In addition, it is improper, in determining whether a person of ordinary skill in the art would have been led to this combination of references, to simply use “that which the inventor taught against its teacher.” *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002), citing *W.L. Gore & Assocs.*, 837 F.2d 469, 473 (Fed. Cir. 1988)(“[t]here must be reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant’s disclosure”); *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371 (Fed. Cir. 2004)(“the suggestion to combine references must not be derived by hindsight from knowledge of the invention itself.”) Specifically, the Examiner may not use the Applicants disclosure of the use of the claimed compositions in methods for treating a central nervous system neoplasm of a patient as a blueprint to reconstruct the claimed invention from the isolated pieces of prior art cited, as this contravenes the statutory mandate of § 103 which requires judging obviousness at the time the invention was made. The Applicants respectfully assert that absent the teaching of the instant invention, the ‘986 patent can not be combined with the ‘173 patent to render obvious compositions which provide extended release of an antineoplastic agent into said anatomic area and which, for a period of at least seven days, release of said antineoplastic agent at an approximately constant rate.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 103(a).

### **FEES**

The Applicants believe that all fees required in connection with the filing of this Response have been provided. Nevertheless, the Commissioner is hereby authorized to charge any fees due in connection with the filing of this Response to our Deposit Account, No. **06-1448**, Reference **GPT-030.01**.

### **CONCLUSION**

The Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants’ Agent would expedite prosecution of the above-

identified application, the Examiner is urged to contact the undersigned.

Respectfully submitted,  
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